

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES**TRANSMITTAL AND NOTICE OF APPROVAL OF  
STATE PLAN MATERIAL  
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER

04 - 016

2. STATE

Virginia

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL  
SECURITY ACT (MEDICAID)

4. PROPOSED EFFECTIVE DATE

December 1, 2004

TO: REGIONAL ADMINISTRATOR  
CENTERS FOR MEDICARE & MEDICAID SERVICES  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

5. TYPE OF PLAN MATERIAL (Check One)

☐ NEW STATE PLAN☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate transmittal for each amendment)

6. FEDERAL STATUTE/REGULATION CITATION

42 CFR Part 447

7. FEDERAL BUDGET IMPACT

a. FFY 2005 \$ (5.15 million)

b. FFY 2006 \$ (5.15 million)

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Attachment 4.19B, pp. 7.3, 7.4, 7.5, and 8 of  
159. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION  
OR ATTACHMENT (If Applicable)

Replaces the same pages

10. SUBJECT OF AMENDMENT

~~Discontinue Resource Test and Counting of Earned Income for Family and Children's Groups~~

Pharmacy Reimbursement: Virginia Maximum Allowable Cost (VMAc) for Generic Drugs

GOVERNOR'S REVIEW (Check One)

- ☐
- GOVERNOR'S OFFICE REPORTED NO COMMENT
- <sup>2005</sup>
- 
- ☐
- COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
- 
- ☐
- NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

☒ OTHER, AS SPECIFIED

Secretary of Health and Human Resources

12. SIGNATURE OF STATE AGENCY OFFICIAL

13. TYPED NAME

Patrick W. Finnerty

14. TITLE

Director

15. DATE SUBMITTED

09/29/2004

16. RETURN TO

Dept. of Medical Assistance Services  
600 East Broad Street, #1300  
Richmond VA 23219

Attn: Regulation Coordinator

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED

10/4/04

18. DATE APPROVED

NOV 16 2004

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL

12/1/04

20. SIGNATURE OF REGIONAL OFFICIAL

Roseanne Egan for Nancy B. O'Connor

21. TYPED NAME

NANCY B. O'CONNOR

22. TITLE

ACTING REGIONAL ADMINISTRATOR

23. REMARKS

**STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT**

State of VIRGINIA

**METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES -- OTHER TYPES  
OF CARE  
ESTABLISHMENT OF RATE PER VISIT**

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Fee-for-service providers: pharmacy. (12VAC30-80-40)

Payment for pharmacy services shall be the lowest of items 1 through 4 (except that items 1 and 2 will not apply when prescriptions are certified as brand necessary by the prescribing physician in accordance with the procedures set forth in 42 CFR 447.331 (c) if the brand cost is greater than the Centers for Medicare and Medicaid Services (CMS) upper limit or VMAC cost) subject to the conditions, where applicable, set forth in subdivisions 6 and 7 of this section:

1. The upper limit established by the CMS for multiple source drugs pursuant to 42 CFR 447.331 and 447.332, as determined by the CMS' Upper Limit List plus a dispensing fee. If the agency provides payment for any drugs on the CMS' Upper Limit List, the payment shall be subject to the aggregate upper limit payment test.
2. The Virginia Maximum Allowable Cost (VMAC) established by DMAS or its designated contractor to be inclusive of appropriate generic drug products plus a dispensing fee. The VMAC methodology shall be the higher of either: (i) the lowest wholesale acquisition cost (WAC) plus 10 percent, OR (ii) the second lowest WAC plus six percent. In developing the VMAC for generic pharmaceuticals, the department or its designated contractor shall:
  - a. Identify three different suppliers, including either manufacturers or wholesalers, that are able to supply, in sufficient quantities, pharmaceutical products. The drugs considered must be listed as therapeutically and pharmaceutically equivalent in the Food and Drug Administration's most recent version of the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"). Pharmaceutical products that are not available from three different suppliers, including either manufacturers or wholesalers, shall not be subject to the VMAC list.
  - b. Identify that the use of a VMAC rate is lower than the Federal Upper Limit (FUL) for the drug. The FUL is a known, widely published price provided by CMS; and
  - c. Distribute the list of state VMAC rates to pharmacy providers in a timely manner prior to the implementation of VMAC rates and subsequent modifications. DMAS shall publish on its' website, each month, the information used to set the Commonwealth's prospective VMAC rates, including, but not necessarily limited to:
    - (i) The identity of applicable reference products used to set the VMAC rates;

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Supersedes  
TN No. 03-09

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- (ii) The Generic Code Number (GCN) or National Drug Code (NDC), as may be appropriate, of reference products;
  - (iii) The difference by which the VMAC rate exceeds the appropriate WAC price; and
  - (iv) The identity and date of the published compendia used to determine reference products and set the VMAC rate. The difference by which the VMAC rate exceeds the appropriate WAC price shall be at least or equal to 10 percent above the lowest-published wholesale acquisition cost for products widely available for purchase in the Commonwealth and shall be included in national pricing compendia.
- d. Development of a VMAC rate that does not have a FUL rate shall not result in the use of higher-cost innovator brand name or single source drugs in the Medicaid program.
- e. DMAS or its designated contractor shall:
- (i) Implement and maintain a procedure to add or eliminate products from the list, or modify VMAC rates, consistent with changes in the fluctuating marketplace. DMAS or its designated contractor will regularly review manufacturers' pricing and monitor drug availability in the marketplace to determine the inclusion or exclusion of drugs on the VMAC list; and
  - (ii) Provide a pricing dispute resolution procedure to allow a dispensing provider to contest a listed VMAC rate. DMAS or its designated contractor shall confirm receipt of pricing disputes within 24 hours, via telephone or facsimile, with the appropriate documentation of relevant information, e.g., invoices. Disputes shall be resolved within three business days of confirmation. The pricing dispute resolution process will include DMAS' or the contractor's verification of accurate pricing to ensure consistency with marketplace pricing and drug availability. Providers will be reimbursed, as appropriate, based on findings. Providers shall be required to use this dispute resolution process prior to exercising any applicable appeal rights.
3. The Estimated Acquisition Cost (EAC) which shall be based on the published Average Wholesale Price (AWP) minus a percentage discount established by the General Assembly (as set forth in subdivision 7 of this section) or, in the absence thereof, by the following methodology set out in subdivisions a through c below.

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- a. Percentage discount shall be determined by a statewide survey or providers' acquisition cost.
  - b. The survey shall reflect statistical analysis of actual provider purchase invoices.
  - c. The agency will conduct surveys at intervals deemed necessary by DMAS.
4. The provider's usual and customary charge to the public, as identified by the claim charge.
5. Payment for pharmacy services will be as described above; however, payment for legend drugs will include the allowed cost of the drug plus only one dispensing fee per month for each specific drug. Exceptions to the monthly dispensing fees shall be allowed for drugs determined by the department to have unique dispensing requirements. The dispensing fee of \$3.75 (effective July 1, 2003) shall remain in effect.
6. The Program pays additional reimbursement for the unit dose dispensing system of dispensing drugs. This service is paid only for patients residing in nursing facilities. Reimbursements are based on the allowed payments described above plus the unit dose per capita fee to be submitted by the pharmacy for unit dose dispensing services to a nursing home resident. Only one service fee per month may be submitted by the pharmacy for each patient receiving unit dose dispensing services. Multi-source drugs will be reimbursed at the maximum allowed drug cost for specific multiple source drugs, as identified by the state agency or CMS' upper limits as applicable. All other drugs will be reimbursed at drug costs not to exceed the estimated acquisition cost determined by the state agency. The original per capita fee shall be determined by a DMAS analysis of costs related to such dispensing, and shall be re-evaluated at periodic intervals for appropriate adjustment. The unit dose dispensing fee is \$5.00 per recipient per month per pharmacy provider.
7. Determination of EAC was the result of a report by the Office of the Inspector General that focused on appropriate Medicaid marketplace pricing of pharmaceuticals based on the documented costs to the pharmacy. An EAC of AWP minus 10.25% shall become effective July 1, 2002.

The dispensing fee of \$3.75 (effective July 1, 2003) shall remain in effect, creating a payment methodology based on the previous algorithm (least of 1 through 4 of this subsection above) plus a dispensing fee where applicable.

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Home infusion therapy.

- A. The following categories shall have a pharmacy service day rate payment allowable: hydration therapy, chemotherapy, pain management therapy, drug therapy, total parenteral nutrition (TPN). The service day rate payment for the pharmacy component shall apply to the basis components and services intrinsic to the therapy category. Submission of claims for the per diem rate shall be accomplished by use of the CMS 1500 claim form.
- B. The cost of the active ingredient or ingredients for chemotherapy, pain management and drug therapies shall be submitted as a separate claim through the pharmacy program, using standard pharmacy format. Payment for this component shall be consistent with the current reimbursement for pharmacy services. Multiple applications of the same therapy shall be reimbursed one service day rate for the pharmacy services. Multiple applications of different therapies shall be reimbursed at 100% of standard pharmacy reimbursement for each active ingredient.

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TN No. 03-09

Approval Date **NOV 16 2004**

Effective Date 12-01-04